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March 12, 1985

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TO: Myron Karman, Esq.
Office of the Executive Legal Director
U.S. Nuclear Regulatory Commission

FROM: Robert J. Ross
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RE: Docket No. 50-54, Facility Operating License No. R-81

On December 28, 1984, Union Carbide Subsidiary "B" Inc., a Delaware Coporation and holder of Nuclear Regulatory Commission ("NRC") Facility Operating License No. R-81 (the "License") joined with Cintichem, Inc. ("Cintichem"), a Delaware Corporation to file a joint application with NRC to transfer the License to Cintichem. Cintichem is a wholly-owned Delaware subsidiary of Medi-Physics, Inc., a Delaware corporation. Medi-Physics, Inc. is a wholly-owned subsidiary of Hoffmann-La Roche, Inc., a New Jersey corporation that is owned by Curacao Pharmholding, N.V., a Curacao Corporation. Curacao Pharmholding N.V. is wholly-owned by Sapac, Ltd., a New Brunswick (Canada) corporation. Sapac, Ltd. is publicly owned and its shares are traded as a unit with shares of F. Hoffmann-La Roche and Company, Ltd., a corporation registered in Switzerland.

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The joint application seeks to transfer the License for the 5-megawatt Sterling Forest research reactor located in Tuxedo, New York, which produces medical isotopes for use in the radiopharmaceutical industry.

The License was initially issued to Union Carbide Corporation in 1960 and renewed by Amendment No. 21 issued as of September 14, 1984, which extended the License through June 30, 2000. The License and its extension permits reactor operation pursuant to Section 104(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. § 2134(b)). Transfer of the License is sought pursuant to Section 184 of the Atomic Energy Act of 1954, as amended, (42 U.S.C. §2234) and Section 109 of Public Law 98-553 (98 Stat. 2825). The latter was signed into law by the President on October 30, 1984 and specifically authorizes the NRC to transfer Facility Operating License No. R-81 to a United States entity or corporation ultimately owned or controlled by a foreign corporation upon a finding by the NRC that such transfer is not inimical to the common defense and security of the United States or to the public health and safety.

At a meeting held February 5, 1985 at NRC offices in Bethesda, Maryland between NRC counsel and staff and Union Carbide/Cintichem counsel and management, it was requested that counsel for Union Carbide/Cintichem file a memorandum with the NRC staff counsel discussing the section of the Atomic Energy

Act of 1954, as amended, under which the transfer of the License to Cintichem should be effected. For the reasons given below, it is our opinion that Facility Operating License No. R-81 should be transferred to Cintichem pursuant to Section 104(b) of the Atomic Energy Act of 1954, as amended.

From its inception in 1960 as a research reactor owned by Union Carbide, the Sterling Forest Reactor has operated as a Section 104(b) licensed reactor. The reason for its being licensed under Section 104(b) initially and as renewed in 1984 is that the facility is devoted to production of medical isotopes used in medical therapy and in medical research. Section 104 states as follows:

Section 104. Medical Therapy and Research and Development:

- a. The Commission is authorized to issue licenses to persons applying therefore for utilization facilities for use in medical therapy. In issuing such licenses the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for such purposes and to impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public.

- b. As provided for in subsection 102(b) or 102(c), or where specifically authorized by law, the Commission is authorized to issue licenses under this subsection to persons applying therefore for utilization and production facilities for industrial or commercial purposes. . . [42 USC § 2134(a) and (b)].

Further, NRC regulations provide:

A class 104 license will be issued to an applicant who qualifies for any one or more of the following: to transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess or use:

- (a) A utilization facility for use in medical therapy; or

- (b)(1) A production or utilization facility the construction or operation of which was licensed pursuant to subsection 104 b of the Act prior to December 19, 1970 . . . [10 CFR § 50.21].

In the present instance, the Sterling Forest reactor is devoted entirely to the production of radiopharmaceuticals for use in medical therapy and research. The facility was originally constructed and operated under a Section 104(b) license. The Section 104(b) license has been in effect since 1960. Construction and operation of the Sterling Forest reactor was originally licensed pursuant to Section 104(b), prior to December 19, 1970. The regulations were reviewed again in 1984 and the license was renewed by the NRC under Section 104(b). The joint application does not seek a new license; but, an amendment to the existing license to substitute Cintichem for the present licensee.

Myron Karman, Esq.
March 12, 1985
Page 5

DOUB AND MUNTZING
CHARTERED

Therefore, in all respects, this reactor meets the requirements of Section 104(b) of the Atomic Energy Act of 1954, as amended and of the Commission's regulations at 10 CFR § 50.21.

For the above reasons, when Facility Operating License R-81 is amended to effect a license transfer to Cintichem, the License should remain a Section 104(b) license.